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Re-evaluation Decision RVD2011-12

Diclofop-methyl

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Re-evaluation Decision

After a re-evaluation of the herbicide diclofop-methyl, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing diclofop-methyl for sale and use in Canada.

An evaluation of available scientific information found that products containing diclofop-methyl do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of diclofop-methyl uses, new risk reduction measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of diclofop-methyl was first presented in Proposed Re-evaluation Decision PRVD2011-10, *Diclofop-methyl*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of diclofop-methyl as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. The wording of label amendments has been revised for clarity and to reflect current label standards. The revised label amendments are attached as Appendix I. Apart from those revisions, this decision is consistent with the proposed re-evaluation decision stated in PRVD2011-10. To comply with this decision, the registrant of products containing diclofop-methyl will be informed of the specific requirements affecting their product registrations.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Diclofop-methyl has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk reduction measures for Canadian uses of diclofop-methyl. In this decision, the PMRA took into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy [TSMP]).

The USEPA re-evaluated diclofop-methyl and published its conclusions in a 2000 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2011-10, *Diclofop-methyl*.

What Is Diclofop-methyl?

Diclofop-methyl is a post-emergent herbicide used to control annual grasses in agricultural food/feed crops. It acts by inhibiting plant cellular metabolism.

Health Considerations

Can Approved Uses of Diclofop-methyl Affect Human Health?

Diclofop-methyl is unlikely to affect your health when used according to the revised label directions.

People could be exposed to diclofop-methyl through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that diclofop-methyl was unlikely to affect human health provided that risk reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Diclofop-methyl is currently registered in Canada for use on agricultural food/feed crops and could be used in other countries on crops that are imported into Canada. MRLs of 0.1 ppm diclofop-methyl were established for barley, triticale and wheat on 18 March 2011 as indicated

in Established Maximum Residue Limit, *Established Maximum Residue Limits for Pesticides/Commodities Currently Registered in Canada Previously Covered by the 0.1 Parts Per Million General Maximum Residue Limit*.

Environmental Considerations

What Happens When Diclofop-methyl Is Introduced Into the Environment?

Diclofop-methyl is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target terrestrial and aquatic species could be exposed to diclofop-methyl in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some potential risks of concern.

The USEPA concluded that the reregistration of diclofop-methyl was acceptable provided risk reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk reduction measures are required. Furthermore, the PMRA requires both aquatic and terrestrial buffer zones for diclofop-methyl to protect aquatic organisms and terrestrial plants from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of diclofop-methyl, the PMRA is requiring further risk reduction measures for product labels.

Human Health

- Revised toxicology hazard label statements
- Additional personal protective equipment for handlers
- Closed mixing/loading systems
- Enclosed cab application equipment
- Maximum permitted amount handled per day
- Restricted entry interval

Environment

- Terrestrial and aquatic buffer zones
- Improvements to environmental label statements

Appendix I lists all required label amendments.

Other Information

Any person may file a notice of objection[3] regarding this decision on diclofop-methyl within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing Diclofop-methyl

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended as follows.

I) The following uses must be removed from the label, including all references to these uses:

Alfalfa
Bromegrass
Carrots
Clover (Red, Alsike and Sweet)
Creeping Red Fescue
Dry Common Beans (Black, White, Kidney, Pinto)
Faba beans
Flax (excluding low linolenic acid varieties)
Lentils
Lima Beans
Onions (Bulb only)
Peas (Field and Processing)
Potatoes
Rapeseed (Canola)
Rye (Spring and Fall)
Russian Wild Rye Grass
Sainfoin (Seed production only)
Snap Common Beans
Soybeans
Sugarbeets
Sunflowers (except Corona)
Tame Buckwheat
Tame Mustard
Triticale
Wheat Grass (Crested & Intermediate).

II) The following label amendments are required to address the overlap between 'British Columbia' and the 'Peace River region of British Columbia'.

On the primary panel

Replace: *"FOR SALE FOR USE IN EASTERN CANADA AND BRITISH COLUMBIA ONLY"*

With: *"FOR SALE FOR USE ONLY IN EASTERN CANADA AND THE PROVINCE OF BRITISH COLUMBIA EXCLUDING THE PEACE RIVER REGION"*

Under DIRECTIONS FOR USE

Replace: *"EASTERN CANADA AND BRITISH COLUMBIA"*

With: *"EASTERN CANADA AND THE PROVINCE OF BRITISH COLUMBIA EXCLUDING THE PEACE RIVER REGION"*

III) The following statements must be included on the primary display panel of the label:

POTENTIAL SKIN SENSITIZER

IV) The following statements must be included in a section entitled PRECAUTIONS.

Potential skin sensitizer.

Wear coveralls over long sleeved shirt and long pants, chemical-resistant gloves, socks, and chemical-resistant footwear during mixing, loading, application, clean up and repair. Wear goggles or face shield during mixing/loading.

Applicators must use an enclosed cab.

Handlers performing tasks for which engineering controls are not feasible, such as spill cleanup, must wear coveralls over long-sleeved shirt and long pants, protective eyewear, chemical-resistant gloves, chemical-resistant footwear, chemical-resistant apron and a respirator.

When a respirator is required, handlers must wear either a respirator with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH/MSHA/BHSE approved canister approved for pesticides.

DO NOT enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours.

V) The following statements must be included in a section entitled DIRECTIONS FOR USE.

Mixers/loaders must use a closed system that transfers liquid in a manner that prevents release of the liquid or any vapour.

Maximum of one application of diclofop-methyl per season.

Mixer/loaders must not handle more than 67 kg a.i. per day per worker. Applicators using ground equipment must not handle more than 144 kg a.i. per day per worker. Applicators using aerial equipment must not handle more than 92 kg a.i. per day per worker.

As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

Aerial application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply when wind speed is greater than 16 km/h at flying height at the site of application. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length MUST NOT exceed 65% of the wing- or rotorspan.

Buffer zones:

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:				
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial Habitat
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer*	Wheat, Barley		2	1	1	1	3
Aerial	Wheat, Barley	Fixed wing	45	1	5	1	100
		Rotary wing	30	1	5	1	85

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

VI) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS**.

TOXIC to aquatic organisms, birds, small mammals and non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.